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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,176	02/11/2004	James D. McIninch	16517.308	1905
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ARNOLD & PORTER LLP ATTN: IP DOCKETING DEPT. 555 TWELFTH STREET, N.W. WASHINGTON, DC 20004-1206			EXAMINER SMITH, CAROLYN L	
			ART UNIT 1631	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/775,176	MCININCH, JAMES D.	
	Examiner	Art Unit	
	Carolyn L. Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2007 and 1/29/07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52,56,57 and 60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52,56,57 and 60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendments and remarks, filed 4/24/07 and 1/29/07, are acknowledged. Amended claims 52 and 60 and cancelled claims 1-51, 53-55, and 58-59 are acknowledged.

Applicant's arguments, filed 4/24/07 and 1/29/07, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 52, 56-57, and 60 are herein under examination.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is directed to computational nucleic acid coding and feature analysis, whereas in contrast the new claims are specifically directed to a method for determining the probability for one or more states for a selected nucleotide in a nucleic acid sequence.

Applicant chooses to defer a title change until later. Therefore, this objection is maintained.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 52, 56-57, and 60 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

This rejection is maintained and reiterated for reasons of record.

Under the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (published in the O.G. notice (1300 OG 142) on 11/22/2005) a method that does not result in a physical transformation of matter MAY be statutory where it recites a concrete, tangible and useful result; i.e. a practical application.

The instant claims are directed to a method for determining a probability for one or more states for a selected nucleotide in a nucleic acid sequence. It is noted that the method does not result in a physical transformation of matter, nor is any concrete, tangible and useful result produced/recited. Therefore, these claims are not statutory.

Applicant refers to MPEP 2106 stating that a statutory process “must be limited to a practical application of the abstract idea or mathematical algorithm in the technological art” and cites the “filtering noise” example. Then Applicant summarizes the claimed invention and states that the algorithm found in the claims has a “practical application” as such methods are widely used for identifying coding sequences of DNA. This statement is found unpersuasive as a practical application is one that is directed to a “concrete, tangible, AND useful” result. The

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question is thus whether the final result achieved by the claimed invention is a result that satisfies all three criteria of being concrete, tangible, and useful. In determining if the instant claims are useful, tangible, and concrete, the Examiner must determine each standard individually. For a claim to be “concrete,” the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. For a claim to be “tangible,” the claim must set forth a practical application of the invention that produces a real-world result. For a claim to be “useful,” the claim must produce a result that is specific, substantial, and credible.

Furthermore, the useful, tangible, and concrete result must be explicitly recited in the claim itself or inherently flow through therefrom, rather than merely addressed in the specification.

While the instant claims may produce a concrete and useful result, there is no tangible result. The instant claims are drawn to computational means for determining a probability for one or more states for more than one selected nucleotide. However, as claimed, the method does not include a real world result. For example, the method as claimed may take place entirely within the confines of a computer or human mind without any communication to the outside world. A tangible requirement requires that the claim must set forth a practical application of the computational steps to produce a real-world result. Applicant argues that the instant invention removes noise in a nucleic acid sequence. This statement is found unpersuasive as there is no noise removal limitation in the instant claims. No tangible result is recited in the claims; thus the instant claims do not include a practical application.

Thus, as the claims do not recite a physical transformation or a communication of a result in a tangible form to one performing the method, the claims are not statutory. Amending the

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claims to recite a step of outputting the result or a physical transformation, would nullify this rejection.

Claims Rejected Under 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

LACK OF WRITTEN DESCRIPTION

Claims 52, 56, 57, and 60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time of the invention was filed, had possession of the claimed invention.

NEW MATTER

Applicant states that written support for the claims can be found in prior claims 53, 54, 55, and the originally filed specification, such as on page 47.

Claims 52, 57, and 60 recite the term “selected” which is not supported in the passages of the specification listed above. The specification states a single nucleotide, such as on page 21, line 8, but it makes no mention of whether this nucleotide was selected or randomly chosen. This rejection is maintained.

Applicant argues that the Examiner’s position regarding the limitation “selected” is a red herring and that the technician practicing the method will know whether it is selected. This

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statement is found unpersuasive as there is no written support for this selected limitation.

Applicants point to pages 25 and 26 of the instant specification. This passage is found unpersuasive in providing written support for the term “selected”, because something that “is being examined” does not mean the same thing as something that is “selected”.

Claim 52 (lines 12-13) recites the phrase “wherein the value produced by said bias function is at least different in one state within all of said states for said selected nucleotide” and claim 60 recites “the value produced by said bias function” which are not supported in the passages of the specification listed above. The scope of the claims is broader than the support found in the specification. For example, as stated on page 21, lines 1-6, bias can be the value of one for at least one state and a value other than one for at least one state. However, this does not provide written support that “the value produced by said bias function is at least different in one state within all of said states for said selected nucleotide” or “the value produced by said bias function”, which differ in scope.

Regarding “value produced by said bias function”, Applicant points to support on page 18, line 17, of the specification which states “‘Bias’ is a set of one or more values that are used in the Bias Function”. This statement is unpersuasive for providing written support because values “being used in” and a value “produced by” are different as the first mentioned may be used to get the result while the latter can be interpreted *to be* the result. Applicant argues that the value produced by the bias function is the bias as represented by the conditions of the bias function. This is found unpersuasive as “the value produced” can be interpreted to be a probability after having applied the bias function, as recited in step d) of instant claim 52.

Claim 52 recites an equation of $P(f | s)$ with " $\Phi(i)$ " which does not appear to have adequate support in the originally filed disclosure. This rejection is necessitated by amendment.

Because the introduction of phrases "selected", "wherein the value produced by said bias function is at least different in one state within all of said states for said selected nucleotide", "the value produced by said bias function", and equation of $P(f | s)$ with " $\Phi(i)$ " lacks written basis for amended claims 52, 57, and 60, as filed on 4/24/07, these phrases are considered to be NEW MATTER. Claim 56 is also rejected due to its dependency from claim 52.

Claim Rejections – 35 U.S.C. 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the

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breadth of the claims. The Board also stated that although the level of the skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

LACK OF SCOPE OF ENABLEMENT

Claims 52, 56, 57, and 60 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed invention.

This rejection is necessitated by amendment.

Claims 52, 56, 57, and 60 are rejected because the specification, while being enabling for the following:

Initial oligonucleotide probability	p. 21, equation I,
Transition probability	p. 22, equation II,
Nucleic acid sequence probability	p. 23, equation III, and
Probability for each nucleotide state	p. 24, equation IV,

the specification does not reasonably provide enablement for any method of computation for determining the above probabilities or the equation now present in instant claim 52 which differs from equation IV with the $\Phi(i)$. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The instant application fails to provide guidance to one of ordinary skill in the art for generating the probability values of the following by any other means than by the four equations

indicated above. The specification does not provide or suggest what any other substitutable methods of computation including equation IV with $\Phi(i)$ which could be for the above probability determinations thus not enabling one of ordinary skill in the art to know what calculations to perform. While the specification provides some guidance for a method of determining a probability value for the above listing using the particular equations or values disclosed, the specification does not provide guidance for a method of determining the probability by any other means. The specification does not provide working examples of the methods described using any other means of computing the described probability values. While working examples are not, per se, required, the specification must provide adequate guidance such that one of skill in the art could practice the invention without undue experimentation. Given the lack of descriptive working examples in the specification, and the unpredictability of generating probability values, the specification as filed is not enabling for any method of determining the listed probability values as claimed. The instant application is only enabled for the above-mentioned computational means of the four probabilities.

Applicant submitted a declaration to introduce evidence that the specification as originally filed would have enabled a person skilled in the art to practice the methods of the claims. The evidence provided is unpersuasive as it only comprises conclusory statements.

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 52, 56, 57, and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. These rejections are necessitated by amendment.

The preamble of claim 52 is directed to method for gene prediction; however, the body of the claim does not recite any gene prediction. Therefore, it is unclear if the preamble or the body of claim 52 is controlling the metes and bounds of the claim. Clarification of this issue via clearer claim wording is requested. Claims 56, 57, and 60 are also rejected due to their dependency from claim 52.

Claims 52 (line 12) and 60 (line 1) recite the limitation “the value” which lacks clear antecedent basis. Applying a bias function to a plurality of probabilities would create a plurality of values. Therefore, it is unclear to which particular “value” is being referred in the limitation. Clarification of this issue via clearer claim wording is requested. Claims 56 and 57 are also rejected due to their dependency from claim 52.

Claim 52 recites the limitation “is at least different in one state within all of the states” which is vague and indefinite. It is unclear what Applicants mean by this limitation. Is a value different in one state from the other states? Is there a state within the other states? Clarification of this issue via clearer claim wording is requested. Claims 56, 57, and 60 are also rejected due to their dependency from claim 52.

Claim 52 is vague and indefinite due to the lack of clarity in the following terms: f , S , P_f , P_i , and Φ . It is unclear as to what are the metes and bounds of these terms. A listing of the

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exact definitions of these terms in claim 52 would clarify this issue. Claims 56, 57, and 60 are also rejected due to their dependency from claim 52.

Applicant states that claim language must be analyzed in light of the application, the prior art teachings, and the claim interpretation from one of ordinary skill in the art. This is found unpersuasive as it is still unclear as to whether Applicant intends to use definitions from the art or those in the specification. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735.

June 25, 2007

/Carolyn Smith/
Primary Examiner
AU 1631